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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/817,704	08/25/1997	ANTHONIUS J. SWAAK	P8214-7002	8580
7590	12/04/2003		EXAMINER	
ARENT FOX KINTER PLOTKIN & KAHN, PLLC 1050 CONNECTICUT AVENUE, N.W. SUITE 600 WASHINGTON, DC 20036-5339			EWOLDT, GERALD R	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	08/817,704	SWAAK, ANTHONIUS J.	
	<b>Examiner</b>	<b>Art Unit</b>	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 9/04/03.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 18,20,23-26 and 31-35 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 18,20,23-26 and 31-35 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \*    c) None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ .

6)  Other: \_\_\_\_\_ .

**DETAILED ACTION**

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment and remarks, filed 9/04/03, has been entered.

2. Claims 18, 20, 23-26, and 31-35 are currently pending in this application.

3. In view of Applicant's amendment and response, the previous rejections under the first paragraph of 35 U.S.C. 112 have been withdrawn.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 18, 20, 23-26, and 32-35 stand/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Toshihide et al. (of record), for the reasons of record as set forth in Paper No. 27, and reiterated in Papers No. 30, 35, and 38 mailed 5/21/01, 1/25/02, 9/30/02, and 4/04/03 respectively.

Applicant arguments, filed 9/04/03, have been fully considered but are not found persuasive. Applicant argues that the amending of "comprising" to "consisting of" would "exclude[ing] from the claimed invention a method that includes supplemental steps such as the Toshihide et al. collection of blood."

It is the Examiner's position that the method of Toshihide et al. is still the method of the instant claims. There are two actual steps recited in the instant claims; first, identifying a patient and second, administering EPO. The first step is inherent to the method of Toshihide et al. and the second step was actually performed. Regarding the administration step, Applicant's method would only be distinct from a method that involved the administration of additional drugs with EPO, however, no other drug was administered with EPO in the method of the reference. By Applicant's logic it would seem that it is Applicant's position that any sort of additional steps, at any time, would render the method of the instant claims patentably distinct. For example, by Applicant's logic, if a physician took the patient's temperature before administering EPO, or if the patient ate a vitamin pill with breakfast before going to the physician for administration of EPO, the method would not comprise prior art in the instant case.

7. Claims 18, 20, 23-26, and 31-35 stand/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pettersson et al. (of record), for the reasons of record as set forth in Paper No. 27, and reiterated in Papers No. 30, 35, and 38 mailed 5/21/01, 1/25/02, 9/30/02, and 4/04/03 respectively.

Applicant arguments, filed 9/04/03, have been fully considered but are not found persuasive. Applicant argues that the amending of "comprising" to "consisting of" would exclude the method of Pettersson et al. because the reference also teaches the inclusion of supplemental iron.

It is the Examiner's position that the method of Pettersson et al. is still the method of the instant claims. Note that the EPO of the reference is administered by subcutaneous injection whereas the iron supplement was taken orally. As it is highly unlikely that the patients received injections while swallowing pills, the method of the reference still "consists of" administering EPO, i.e., the method consists of administering EPO alone.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 18, 20, 23-26, and 31-35 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

- A) "A method of treating morning stiffness, loss of grip strength, painful joints, or swollen joints" (Claim 18).
- B) "A method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level" (Claim 20)

Applicant's amendment, filed 9/30/98, fails to assert that no new matter has been added. However, Applicant does assert that support for the claims can be found at pages 3-13, i.e., essentially in the entire specification. A careful review of the specification shows that the application was filed reciting only "Use" claims. Actual method claims were submitted approximately a year post-filing. Accordingly, specific support for the newly claimed method must be disclosed in the specification. The specification, however, discloses only a method of treating rheumatoid arthritis and a method of treating "chronic inflammations". No methods as set forth above are disclosed.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. **Please Note:** inquiries of a general nature or relating

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to the status of this application should not be directed to the Examiner but rather should be directed to the Technology Center 1600 Customer Service Center at (703) 308-0198.

G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600  
November 26, 2003



11/26/03

**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINEE**